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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,443	09/02/2004	Ugur Sahin	16034US01	1542

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EXAMINER	
HALVORSON, MARK	
ART UNIT	PAPER NUMBER
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,443	SAHIN ET AL.	
	Examiner	Art Unit	
	Mark Halvorson	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-117* is/are pending in the application.

4a) Of the above claim(s) *17-32, 36-43, 47-56, 68, 70-72, 78-81, 93 and 94* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-16,33-35,44-46,57-67,69,73-77,82-92 and 95-117.

DETAILED ACTION

Claims 1-117 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, 4, 5, 9 drawn to a pharmaceutical composition comprising an agent that inhibits the expression or activity of a protein encoded by a nucleic acid.

Additionally, Applicants are required under 35 U.S.C. 121 to elect a single tumor antigen nucleic acid from SEQ ID NOs: 1-5, 19-21, 29, 31-33, 37, 39, 40, 54-57, 62, 63, 70, 74, 85-88 because the nucleic acids present structurally and functionally distinct inventions not a species.

Group 2, claim(s) 2-6, 9 drawn to drawn to a pharmaceutical composition comprising an agent with tumor-inhibiting activity which is selective for cells expressing a protein encoded by a nucleic acid.

Additionally, Applicants are required under 35 U.S.C. 121 to elect a single tumor antigen nucleic acid from SEQ ID NOs: 1-5, 19-21, 29, 31-33, 37, 39, 40, 54-57, 62, 63, 70, 74, 85-88 because the tumor antigens present structurally and functionally distinct inventions not a species.

Group 3, claim 7-9, 11-16 drawn to a pharmaceutical composition, comprising an agent which, selectively increases the amount of complexes between an HLA molecule and a tumor-associated antigen.

Additionally, Applicants are required under 35 U.S.C. 121 to elect a single tumor antigen nucleic acid from SEQ ID NOs: 1-5, 19-21, 29, 31-33, 37, 39, 40, 54-57, 62, 63, 70, 74, 85-88 because the tumor antigens present structurally and functionally distinct inventions not a species.

Group 4, claim 10-16 drawn to a pharmaceutical composition.

Additionally, Applicants are required under 35 U.S.C. 121 to elect a single tumor antigen nucleic acid from SEQ ID NOs: 1-5, 19-21, 29, 31-33, 37, 39, 40, 54-57, 62, 63, 70, 74, 85-88 complexed with an HLA molecule because the tumor antigens present structurally and functionally distinct inventions not a species.

Group 5, claims 33-35, drawn to a method of diagnosing a disease characterized by expression of a tumor associated antigen

Additionally, Applicants are required under 35 U.S.C. 121 to elect a single tumor antigen nucleic acid from SEQ ID NOs: 1-5, 19-21, 29, 31-33, 37, 39, 40, 54-57, 62, 63, 70, 74, 85-88 because the tumor antigens present structurally and functionally distinct inventions not a species.

Group 6, claims 44-46 drawn to a method for determining regression

Additionally, Applicants are required under 35 U.S.C. 121 to elect the tumor antigen or group of tumor antigen nucleic acids from SEQ ID NOs: 1-5, 19-21, 29, 31-33, 37, 39, 40, 54-57, 62, 63, 70, 74, 85-88 because the tumor antigens present structurally and functionally distinct inventions not a species.

Applicant is requested to **identify the combination of tumor associated antigens** to be examined.

Group 7, claim 57, 114-117 drawn to a method for treating a disease characterized by the expression of a tumor-associated antigen comprising administering an antibody binding to the tumor associated antigen.

Additionally, Applicants are required under 35 U.S.C. 121 to elect a single tumor antigen nucleic acid from SEQ ID NOs: 1-5, 19-21, 29, 31-33, 37, 39, 40, 54-57, 62, 63, 70, 74, 85-88 because the nucleic acids present structurally and functionally distinct inventions not a species.

Group 8, claim 57, 114-117 drawn to a method for diagnosing a disease characterized by the expression of a tumor-associated antigen comprising administering an antibody binding to the tumor associated antigen.

Additionally, Applicants are required under 35 U.S.C. 121 to elect a single tumor antigen nucleic acid from SEQ ID NOs: 1-5, 19-21, 29, 31-33, 37, 39, 40, 54-57, 62, 63, 70, 74, 85-88 because the nucleic acids present structurally and functionally distinct inventions not a species.

Group 9, claim 57, 114-117 drawn to a method for monitoring a disease characterized by the expression of a tumor-associated antigen comprising administering an antibody binding to the tumor associated antigen.

Additionally, Applicants are required under 35 U.S.C. 121 to elect a single tumor antigen nucleic acid from SEQ ID NOs: 1-5, 19-21, 29, 31-33, 37, 39, 40, 54-57, 62, 63, 70, 74, 85-88 because the nucleic acids present structurally and functionally distinct inventions not a species.

Group 10,claims 61-63, drawn to a method of treating a patient having a disease characterized by expression of a tumor-associated antigen comprising introducing a T cell into the patient.

Additionally, Applicants are required under 35 U.S.C. 121 to elect a single tumor antigen nucleic acid from SEQ ID NOs: 1-5, 19-21, 29, 31-33, 37, 39, 40, 54-57, 62, 63, 70, 74, 85-88 because the nucleic acids present structurally and functionally distinct inventions not a species.

Group 11, claims 64- 67 drawn to a method of treating a patient having a disease characterized by expression of a tumor-associated antigen comprising introducing transfected host cells into the patient.

Additionally, Applicants are required under 35 U.S.C. 121 to elect a single tumor antigen nucleic acid from SEQ ID NOs: 1-5, 19-21, 29, 31-33, 37, 39, 40, 54-57, 62, 63, 70, 74, 85-88 because the nucleic acids present structurally and functionally distinct inventions not a species.

Group 12, claim 69, drawn to a method of treating a patient having a disease characterized by expression of a tumor-associated antigen comprising isolating cells from a patient, culturing the cells and introducing the cells into the patient.

Additionally, Applicants are required under 35 U.S.C. 121 to elect a single tumor antigen nucleic acid from SEQ ID NOs: 1-5, 19-21, 29, 31-33, 37, 39, 40, 54-57, 62, 63, 70, 74, 85-88 because the nucleic acids present structurally and functionally distinct inventions not a species.

Group 13, claims 73- 77 and 98 drawn to a nucleic acid.

Additionally, Applicants are required under 35 U.S.C. 121 to elect a single tumor antigen nucleic acid from SEQ ID NOs: 2-5, 20-21, 29, 31-33, 37, 39, 54-57, 62, 63, 85-88 or nucleic acid encoding SEQ ID NOs: 7-13, 14-18, 23-24, 34-36, 58-61, 64, 65, 89-100 because the nucleic acids present structurally and functionally distinct inventions not a species.

Group 14, claims 82-85 drawn to a protein.

Additionally, Applicants are required under 35 U.S.C. 121 to elect a single tumor antigen of SEQ ID NOs: 7-13, 14-18, 23-24, 34-36, 58-61, 64, 65, 89-100 or tumor antigen encoded by the nucleic acid of SEQ ID NOs: 2-5, 20-21, 29, 31-33, 37, 39, 54-57, 62, 63, 85-88 because the proteins present structurally and functionally distinct inventions not a species.

Group 15, claims 86-89 drawn to an agent that specifically binds to a protein.

Additionally, Applicants are required under 35 U.S.C. 121 to elect a single tumor antigen of SEQ ID NOs: 6-13, 14-18, 22-24, 30, 34-36, 38, 41, 58-61, 64, 65, 71, 75, 80-84, 89-100 or tumor antigen encoded by the nucleic acid of SEQ ID NOs: 1-5, 19-21, 29, 31-33, 37, 39, 40, 54-57, 62, 63, 70, 74, 85-88 because the proteins present structurally and functionally distinct inventions not a species.

Group 16, claims 90-92 drawn to antibody that binds selectively to a complex of a protein and an MHC molecule.

Additionally, Applicants are required under 35 U.S.C. 121 to elect a single tumor antigen of SEQ ID NOs: 6-13, 14-18, 22-24, 30, 34-36, 38, 41, 58-61, 64, 65, 71, 75, 80-84, 89-100 or tumor antigen encoded by the nucleic acid of SEQ ID NOs: 1-5, 19-21, 29, 31-33, 37, 39, 40, 54-57, 62, 63, 70, 74, 85-88 because the proteins present structurally and functionally distinct inventions not a species.

Group 17, claims 95- 97 , drawn to a kit for detecting expression or abnormal expression of a tumor-associated antigen comprising an agent.

Additionally, Applicants are required under 35 U.S.C. 121 to elect a single tumor antigen nucleic acid from SEQ ID NOs: 1-5, 19-21, 29, 31-33, 37, 39, 40, 54-57, 62, 63, 70, 74, 85-88 because the nucleic acids present structurally and functionally distinct inventions not a species.

Group 18, claim 99, 101, 102, 104-113 drawn to a pharmaceutical composition comprising an agent that inhibits expression or activity of the tumor antigen TPTE.

Additionally, Applicants are required under 35 U.S.C. 121 to elect a single tumor antigen nucleic acid from SEQ ID NOs: 19 and 22 because the nucleic acids present structurally and functionally distinct inventions not a species.

Group 19, claims 100-102, 104-113, drawn to a pharmaceutical composition comprising an agent that inhibits the migration activity and metastisizing activity the tumor antigen TPTE.

Group 20, claim 103, drawn to an antibody which binds to an extracellular protein region.

Additionally, Applicants are required under 35 U.S.C. 121 to elect a single proteins from SEQ ID NOs: 81-82 because the proteins present structurally and functionally distinct inventions not a species.

Claims 17-32, 36-43, 47-56, 68, 70-72, 78-81, 93 and 94, are withdrawn from consideration under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim. See MPEP § 608.01. Upon amendment, the claims will be rejoined to or restricted to the appropriate group.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is

fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding, special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c), 37 C.F.R. 1.475(d)

The invention listed as Groups 1-20 do not relate to a single inventive concept under PCT Rule 1.31 because, under PCT 13.2 they lack the same or corresponding special technical feature for the following reasons:

The technical feature of claim 1 is an agent, such as an antibody, that inhibits expression or activity of a tumor associated protein encoded by SEQ ID NO:1. Millan et al (PNAS, 1987, 84:5311-5315) disclose antibodies to human LDHC4 a protein having an amino acid sequence encoded by a nucleic acid identical to SEQ ID NO:1 of the present application. Thus, Claim 1 lacks the special technical feature.

Thus, the different groups in the present application do not contain a single inventive concept and can be separated accordingly.

SPECIES ELECTION

This application contains claims directed to the following patentably distinct species of the claimed invention. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

(i). Groups 1 and 2 is subject to election of at least one of the disclosed species.

Claims 1 and 2 are generic to a plurality of disclosed patentably distinct species of agents whereby the agents are **(a) antisense nucleic acid** (claim 4) or (b) an **antibody** (claims 5 and 6). The species are independent or distinct because they are structurally different molecules.

(ii). Group 3 is subject to election of at least one of the disclosed species.

Claim 8 is generic to a plurality of disclosed patentably distinct species of agents whereby the agents are **(a) tumor associated antigen (b) nucleic acid which codes for the tumor associated antigen (c) host cell expressing the tumor associated antigen and (d) isolated complexes**. The species are independent or distinct because they are structurally different molecules.

(iii). Group 4 is subject to election of at least one of the disclosed species.

Claim 10 is generic to a plurality of disclosed patentably distinct species of components whereby the components are **(a) tumor associated antigen (b) nucleic acid which codes for the tumor associated antigen (c) antibody (d) antisense nucleic acid and (e) host cell**. The species are independent or distinct because they are structurally different molecules.

(iv). Group 5 is subject to election of at least one of the disclosed species.

Claim 33 is generic to a plurality of disclosed patentably distinct species of components whereby the components are **(a) tumor associated antigen (b) nucleic acid which codes for the tumor associated antigen (c) antibody (d) cytotoxic T cell and (e) helper T cell**. The species are independent or distinct because they are structurally different molecules or cell types.

(v). Group 6 is subject to election of at least one of the disclosed species.

Claim 44 is generic to a plurality of disclosed patentably distinct species of parameters whereby the one or more paramaters are **(a) tumor associated antigen (b) nucleic acid which codes for the tumor associated antigen (c) antibody (d) cytolytic T cell and (e) cytokine-releasingT cell**. The species are independent or distinct because they are structurally different molecules or cell types.

Applicant is requested to **identify the parameters** to be examined.

(vi). Group 10 is subject to election of at least one of the disclosed species.

Claim 61 is generic to a plurality of disclosed patentably distinct species of cell types whereby the cell types are **(a) cytolytic T cell and (b) cytokine releasing T cell**. The species are independent or distinct because they are structurally different molecules or cell types.

(vii). Group 11 is subject to election of at least one of the disclosed species.

Claim 64 is generic to a plurality of disclosed patentably distinct species of immune cell response whereby the immune responses are **(a) B cell, (b) cytolytic T cell and (c) cytokine releasing T cell**. The species are independent or distinct because they are structurally different molecules or cell types.

(viii). Group 17 is subject to election of at least one of the disclosed species.

Claim 95 is generic to a plurality of disclosed patentably distinct species of components whereby the components are **(a) tumor associated antigen (b) nucleic acid which codes for the tumor associated antigen (c) antibodies, and (d)T cell**. The species are independent or distinct because they are structurally different molecules or cell types.

(ix). Groups 18 and 19 are subject to election of at least one of the disclosed species.

Claims 99 and 100 are generic to a plurality of disclosed patentably distinct species of agents whereby the agents being **(a) antibody claims 101-102 (b) antisense nucleic acid (claims 104-105) (c) an RNA interference molecule (claims 110) or a small molecule (claims 111-113).** The species are independent or distinct because they are structurally different molecules or cell types.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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